

REMARKS/ARGUMENTS

Applicant acknowledges receipt of the Office Action dated October 13, 2010. By this Response, claims 13 and 24 are amended, and claims 23 and 33 are cancelled. Claims 13-15, 17, 19-21, 24, 25, 27-29, and 31 are now pending in the application. The Examiner rejected claims 13-15, 17, 19-21, 23-25, 27, 28, 31, and 33 under 35 U.S.C. §103 as being unpatentable over *Pickford et al.*, WO 03/089023 ("*Pickford*") in view of *O'Brien et al.*, U.S. Patent No. 7,488,343 ("*O'Brien*"). Claim 29 is rejected as being unpatentable over *Pickford* in view of *O'Brien* and further in view of *Rosenberg*, U.S. Patent No. 5,185,075 ("*Rosenberg*"). The Examiner has rejected claims 13-15, 17, 19-21, 23-25, 27-29, 31, and 33 under 35 U.S.C. §103 as being unpatentable over *Cooper*, U.S. Patent No. 5,211,832 ("*Cooper*") in view of *Pickford*. Applicant would like to thank the Examiner for the thoughtful telephone discussion. Applicant believes the pending claims are allowable over the art of record and respectfully requests reconsideration and allowance of all claims.

I. Claims 13-15, 17, 19-21, 24, 25, 27, 28, and 31 are patentable over *Pickford* in view of *O'Brien*.

Applicant respectfully traverses the Examiner's rejection of claims 13-15, 17, 19-21, 24, 25, 27, 28, and 31 under §103 as being unpatentable over *Pickford* in view of *O'Brien*. Applicant submits that the Examiner has not made a *prima facie* case of obviousness in rejecting such claims in that the Examiner has not demonstrated why one of ordinary skill in the art would be motivated to combine the teachings of the cited references to achieve all of the elements recited in the rejected claims. Please note that claims 23 and 33 have been cancelled by this Response.

Claim 13 is an independent claim upon which claims 14, 15, 17, 19-21, and 31 depend. Claim 24 is an independent claim upon which claims 25, 27, and 28 depend. Claims 13 and 24 have been amended to recite "said pits extending through said hard layer into said metal substrate."

Claim 13 also recites "said pits being filled with a softer and more porous material than the hard layer, wherein the softer and more porous material comprises titanium oxide, and

wherein the surface layer comprises a surface area, and wherein said pits being of a diameter about 5 microns and said pits occupying between 15 and 20% of the surface area of the surface layer.” Claim 24 also recites “anodising the implant at a voltage above 50 volts for a period of at least 30 minutes, so as to generate . . . shallow pits in the surface layer which are filled with a somewhat softer and more porous material comprising titanium oxide, wherein the surface layer comprises a surface area, and wherein said pits being of a diameter about 5 microns and occupying between 15 and 20% of the surface area of the surface layer . . . such that in the ion exchange step said more porous material in the pits absorbs biocidal metal to a larger extent than said hard layer.”

As previously noted by the Examiner, nothing in *Pickford* teaches or suggests all such recitations. For instance, in the Office Action dated April 30, 2010, the Examiner concludes that “claim 13 differs from the description of the product of *Pickford* by reciting the surface layer is an anodized hard layer including pits.” (pg. 3, lns. 10-11, emphasis added) In the present Office Action, the Examiner acknowledges that “claim 24 differs from the process of *Pickford* by reciting anodizing at a voltage above 50V.” (pg. 6, lns. 2-3, emphasis added)

The differences between independent claims 13 and 24 and *Pickford* are not embodied by *O'Brien* as *O'Brien* does not teach or suggest the missing recitations of independent claims 13 and 24. The Examiner asserts that “parameters such as voltage may be varied to obtain an oxide layer with the desired characteristics. Choice of a higher voltage . . . would have been expected to produce variations in the oxide layer such as larger openings” (Office Action pg.6, lns. 7-9) However, it appears that *O'Brien's* phosphoric acid process is merely conventional anodising, producing a hard oxide layer. Indeed, *O'Brien* teaches that anodising titanium in phosphoric acid at voltages between 5 and 100 V results in a voltage dependent increase in oxide surface thickness (i.e., producing color variations in the anodised material). (*O'Brien*, col. 11, ln. 59-col. 12, ln. 64) Although *O'Brien* references Figure 7b as depicting a “sample anodized in the phosphoric acid solution at 90 V reveal[ing] a porous structure in the oxide,” the scale of the SEM image clearly shows that the porous structures are much smaller than 1 micron. (*O'Brien*, col. 13, lns. 7-9) As such, nothing in *O'Brien* even suggests that anodising with phosphoric acid produces a surface required by independent claims 13 and 24.

The alternative anodising process using HF taught by *O'Brien* also does not teach or suggest the recitations of claims 13 and 24. *O'Brien* teaches that such alternate process produces a regular array of hollow post-shaped elements with diameters of 70 to about 100 nm. (*O'Brien*, col. 13, lns. 23-24) As shown in Figure 2b, these hollow structures do not extend into the underlying metal 20 and are also considerably smaller than the required pits of claims 13 and 24.

No Motivation to Combine

There is also no motivation to combine the teachings of *O'Brien* with *Pickford* to provide *Pickford* with the missing limitations of claims 13 and 24. For instance, *O'Brien* does not teach or suggest the combination of voltage and duration of anodisation required to achieve the implant recited in claim 13 or the method recited in claim 24.

Instead, *O'Brien* teaches away from the claim 24 requirement of "anodising the implant at a voltage above 50 volts for a period of at least 30 minutes" by emphasizing that: (i) the anodising takes less than 1 minute and (ii) an implant having a "porous structure" of "hollow post-shaped elements" that may function as a reservoir for therapeutic agents is achieved at voltages no more than 30 V using HF electrolyte. (*O'Brien*, col. 2, lns. 62-64; col. 6, lns. 36-38; col. 11, lns. 66-67; col. 12, lns. 60-63)

Moreover, *O'Brien* teaches away from producing pits "of a diameter about 5 microns" and "extending through said hard layer into said metal substrate" as required by claims 13 and 24. Conversely, *O'Brien* teaches hollow post elements of a diameter only of 20-200 nm extending outward from the anodised surface. (*O'Brien*, col. 2, lns. 35-43)

Unexpected Results

The surprising and unexpected results of claims 13 and 24 include a surface that provides both a "hard layer" and "ion exchange." For instance, as required by claim 24, anodising "at a voltage above 50 volts" for the sufficiently long time "of at least 30 minutes" provides the surprising and unexpected result of ion exchange and a hard surface. Although anodising at a

voltage greater than 50 V is a known and conventional process, one of ordinary skill in the art would not expect it to produce good ion exchange properties.

In view of the recitations in independent claims 13 and 24 that are neither taught nor suggested by *Pickford* and *O'Brien*, Applicant respectfully submits that independent claims 13 and 24 are allowable over *Pickford* and *O'Brien*. Consequently, Applicant requests that the Examiner withdraw the §103 rejections of dependent claims 14, 15, 17, 19-21, 25, 27, 28, and 31, since it is submitted that independent claims 13 and 24 are allowable. Dependent claims 14, 15, 17, 19-21, 25, 27, 28, and 31 must be allowable, since they carry all the limitations of the allowable independent claims 13 and 24 to which they refer.

II. Claim 29 is patentable over *Pickford* in view of *O'Brien* and further in view of *Rosenberg*.

Applicant respectfully traverses the Examiner's rejection of claim 29 under §103 as being unpatentable over *Pickford* in view of *O'Brien* and further in view of *Rosenberg*. Applicant submits that the Examiner has not demonstrated why one of ordinary skill in the art would be motivated to combine the teachings of the cited references to achieve all of the elements recited in the rejected claim.

Claim 29 is dependent upon independent claim 24. As noted above in Section I, *Pickford* in view of *O'Brien* does not teach or suggest all recitations of independent claim 24. Nothing in *Rosenberg* teaches or suggests the missing recitations of independent claim 24.

Therefore, Applicant requests that the Examiner withdraw the §103 rejection of dependent claim 29, since it is submitted that independent claim 24 is allowable. Dependent claim 29 must be allowable, since such dependent claim 29 carries all the limitations of the allowable independent claim 24 to which it refers.

III. Claims 13-15, 17, 19-21, 24, 25, 27-29, and 31 are patentable over *Cooper* in view of *Pickford*.

Applicant respectfully traverses the Examiner's rejection of claims 13-15, 17, 19-21, 24, 25, 27-29, and 31 under §103 as being unpatentable over *Cooper* in view of *Pickford*. Applicant submits that the Examiner has not demonstrated why one of ordinary skill in the art would be motivated to combine the teachings of the cited references to achieve all of the elements recited in the rejected claims. Please note that claims 23 and 33 have been cancelled by this Response.

Claim 13 is an independent claim upon which claims 14, 15, 17, 19-21, and 31 depend. Claim 24 is an independent claim upon which claims 25, 27, 28, and 29 depend. Claims 13 and 24 have been amended to recite "said pits extending through said hard layer into said metal substrate." (Emphasis Added) To the contrary, *Cooper* teaches anodising in such a way to produce an oxide layer that is protective of the underlying surface. (*Cooper*, col. 6, lns. 42-63) *Pickford* cannot provide *Cooper* with the missing recitations because, as detailed above, nothing in *Pickford* teaches or suggests all such recitations.

Claim 13 also recites "said pits being filled with a softer and more porous material than the hard layer, wherein the softer and more porous material comprises titanium oxide, and wherein the surface layer comprises a surface area, and wherein said pits being of a diameter about 5 microns and said pits occupying between 15 and 20% of the surface area of the surface layer." Claim 24 also recites "anodising the implant at a voltage above 50 volts for a period of at least 30 minutes, so as to generate . . . shallow pits in the surface layer which are filled with a somewhat softer and more porous material comprising titanium oxide, wherein the surface layer comprises a surface area, and wherein said pits being of a diameter about 5 microns and occupying between 15 and 20% of the surface area of the surface layer . . . such that in the ion exchange step said more porous material in the pits absorbs biocidal metal to a larger extent than said hard layer."

The Examiner has taken the position that "[t]he process recited by applicant differs from the process of *Cooper* by reciting adding ions of a biocidal metal by ion exchange." (Office Action, pg. 3, lns. 10-12, emphasis added) However, *Cooper* implicitly teaches a product and process that lacks the recitations of claims 13 and 24. For instance, *Cooper* teaches that

“[b]ecause aprotic solvents differ . . . the solutions most suitable for one purpose may not be the most suitable for another.” (*Cooper*, col. 4, lns. 17-24) Moreover, the sensitivity of certain characteristics of the materials produced using the process of *Cooper* (e.g., zero current voltage) to subtle changes in the anodising solution (e.g., a 9 percent increase in the total water content of the phosphoric acid component, which constitutes only one part combined with nine parts aprotic solvent) is inconsistent with an expectation that the product and process taught by *Cooper* teaches or suggests the recitations of claims 13 and 24. As such, nothing in *Cooper* teaches or suggests a dense hard surface layer and also shallow pits in the surface layer . . . such that in the ion exchange step . . . the pits absorbs biocidal metal to a larger extent than said hard layer or an anodized hard layer including pits . . . having absorbed biocidal metal material to a larger extent than said hard layer, as required by claims 24 and 13, respectively. Further, there is nothing in *Cooper* that provides any reasonable expectation that the surface created by the *Cooper* process would have the “ion exchange” requirement of claims 13 and 24.

As noted in Section I above, nothing in *Pickford* provides all such missing recitations. In view of the recitations in independent claims 13 and 24 that are neither taught nor suggested by *Cooper* and *Pickford*, Applicant respectfully submits that independent claims 13 and 24 are allowable over *Cooper* and *Pickford*. Consequently, Applicant requests that the Examiner withdraw the §103 rejections of dependent claims 14, 15, 17, 19-21, 25, 27-29, and 31, since it is submitted that independent claims 13 and 24 are allowable. Dependent claims 14, 15, 17, 19-21, 25, 27-29, and 31 must be allowable, since they carry all the limitations of the allowable independent claims 13 and 24 to which they refer.

IV. Conclusion

Applicant respectfully requests reconsideration, allowance of the pending claims and a timely Notice of Allowance be issued in this case. If the Examiner feels that a telephone conference would expedite the resolution of this case, the Examiner is respectfully requested to contact the undersigned.

In the course of the foregoing discussions, Applicant may have at times referred to claim limitations in shorthand fashion or may have focused on a particular claim element. This

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discussion should not be interpreted to mean that the other limitations can be ignored or dismissed. The claims must be viewed as a whole, and each limitation of the claims must be considered when determining the patentability of the claims. Moreover, it should be understood that there may be other distinctions between the claims and the prior art that have yet to be raised but which may be raised in the future.

Respectfully submitted,

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